DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 18, 2014

Baxter Healthcare Corporation
Ms. Tiffany Lin
Regulatory Affairs Specialist
32650 N. Wilson Road
Round Lake, Illinois 60073

Re: K142011
Trade/Device Name: Solution Sets, Extension Sets
Regulation Number: 21 CFR 880.5440
Regulatory Class: II
Product Code: FPA
Dated: July 23, 2014
Received: July 24, 2014

Dear Ms. Lin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Devices
Office of Device Evaluation
Center for Devices and
Radiology Health

Enclosure

Section 4 – Indications for Use

510(K) NUMBER (IF KNOWN):

DEVICE NAME:

Intravenous Administration Sets

Indications for Use:

For the administration of fluids from a container into the patient's vascular system through a vascular access device.

Prescription Use __X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5 – 510(k) Summary

July 23, 2014

OWNER:

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DEVICE NAME:

Trade Name:

Solution Sets, Extension Sets

Table 1. Representative Product Codes for Intravenous Administration Sets

Code Number	Name
ACT5432	Solution Set
ACT5543	CONTINU-FLO Solution Set with DUO-VENT Spike
ACT5612	Extension Set
2C5645	Extension Set
2C5647	Y-Type Extension Set

Common name:

Intravenous Administration Sets

Classification name:

Intravenous Administration Set (21 CFR 880.5440, Product Code FPA)

PREDICATE DEVICES:

Table 2. Predicate 510(k)s

Device	Company	Predicate 510(k)	Clearance date
Radiation Sterilized Administration Sets	Baxter Healthcare	K811078	July 2, 1981
Modified Solution Administration Sets	Baxter Healthcare	K961225	June 21, 1996

DEVICE DESCRIPTION:

The proposed devices, which are the subject of this Special 510(k) premarket notification, consist of IV administration sets, some of which include a needle-accessed injection site (y-site). They are single use disposable devices intended for use for the administration of fluids from a container into the patient's vascular system through a vascular access device. These devices are the same as the current marketed devices, including extension sets and solution sets. The extension sets have been previously cleared under 510(k) premarket notification K811078 (cleared on July 2, 1981) and the solution sets have been previously cleared under 510(k) premarket notification K961225 (cleared on June 21, 1996).

The basis for this premarket notification is a proposed design change to the y-site component currently used in Baxter IV administration sets. The design change is intended to eliminate latex in the current y-site as well as to optimize the manufacturing process. This proposed change does not impact the intended use or the fundamental scientific technology of the device. The product labels are also being updated to add the indications for use statement of the device, update the description to comply with Baxter's labeling standard, update the statement regarding latex, and update references to pump devices.

STATEMENT OF INTENDED USE:

For the administration of fluids from a container into the patient's vascular system through a vascular access device.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The proposed devices are equivalent to Baxter's currently legally marketed devices cleared on July 2, 1981 and June 21, 1996. The proposed modification consists of a design change to the y-site component currently used in Baxter IV administration sets. The proposed y-site consists of an injection molded, copolyester housing assembled to a polyisoprene septum. The y-site allows for access to the patient's vascular system when using a needle to deliver fluid. The design and materials for the proposed modification are similar to the design and materials currently used in Baxter's INTERLINK y-site. All IV administration sets have a sterile, non-pyrogenic fluid path. The intended use and function for the proposed device are equivalent to the predicate devices.

DISCUSSION OF NONCLINICAL TESTS:

Baxter Healthcare Corporation conducts risk analyses and design verification tests based on the result of these analyses. All test results meet their acceptance criteria, and support that the proposed devices are appropriately designed for their intended use.

Performance Data:

The following bench tests were conducted to evaluate the effect of the design modification on the functional performance of the IV administration sets with a y-site:

- Puncture Test
- 7-Day Indwell Test
- Burst Test
- Vacuum Leakage Test
- Solvent Bond Tensile Strength Test
- Solvent Bond Air Pressure Test
- Coring Test
- Insertion Force Test

All tests met the acceptance criteria.

Biocompatibility:

No new materials of construction are being introduced into the IV administration sets without the y-site. Biocompatibility assessment has been conducted on all materials including devices with the proposed y-site, based on ISO-10993-1, Biological Evaluation of Medical Devices for prolonged duration, external communicating device, indirect blood path, and Blue Book Memorandum G95-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing", as recommended in the IV administration sets guidance, "Guidance for Industry and FDA Staff: Intravascular Administration Sets Premarket Notification Submissions [510(k)]".

CONCLUSION:

The data from the non-clinical tests demonstrate that the proposed devices are as safe and effective, and perform as well as or better to the predicate devices.